

REMARKS

Status of the Claims

Claims 18-23, 25-27, 29-34, 39, 40, 43, 46-67 are currently pending.

Claims 18-23, 25-27, 29-34, 39, 40, 43, 46-67 stand rejected.

Claims 18, 19, 21-23, 25-27, 29-32, 39, 43, 45, 47, 48, 51-52, 54-61, 63 and 65 are amended herein and 46-67 are newly added herein. No new matter has been introduced.

35 U.S.C. § 101 Rejection

Claims 18-23, 25-27, 29-34, 39, 40, 43, 46-67 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Specifically, the Examiner first rejected independent system claims 18 and 47 as directed towards a computer based system for assessing the health status or health care of a patient not defined by components of a system. (*See* 04/06/2009 Office Action at 3-4). Applicants herein amend independent claims 18 and 47 (and their dependents where applicable, claims 19, 21-23, 25-27, 29-32, 43, and 48-51, respectively), to specify the requisite components: a microprocessor (*see, e.g.* Specification, ¶ 143; *see also* ¶¶ 67, 134 and ¶¶ 13, 15 in conjunction with ¶ 72); an interface (*see, e.g.* Specification ¶¶ 145, 146; *see also* ¶¶ 142, 138, 139, 67); and a database (*see, e.g.* Specification ¶¶ 141, 143). Because the components of the system are clearly delineated, applicants respectfully request that this rejection be withdrawn for independent claims 18 and 47 and their dependents, 19-23, 25-27, 29-34, 43, 46 and 48-51, respectively.

The Examiner further rejected independent claims 18 and 47 as being directed to functional descriptive material not on any medium. As these claims (and furthermore their dependents where applicable), have been amended to include component parts which operate in accordance with the invention, applicants respectfully request that this rejection be withdrawn for independent claims 18 and 47 and their dependents, 19-23, 25-27, 29-34, 43, 46 and 48-51, respectively.

The Examiner next rejected independent claims 39 and 63 as not fitting into any of the four statutory classes and as directed to computer readable media but not defining the type of media. The specification, however, presents various types of media and at paragraph 137 specifically explains that this “computer-readable media . . . contains the instructions for use by a programmable general purpose computer.” Examples include:

- Paragraph 141 of the specification explains that “the host computer facility can be a server or cluster of servers with associated data storage volumes. . . . Optionally, the network accesses or includes a number of remote database sources providing access to elements both within and without the host computer facility.”
- Paragraph 134 of the specification explains that the system “may comprise a general purpose computer as selectively activated or reconfigured by a computer program stored in the computer.”
- Paragraph 143 of the specification explains that a device upon which the present invention can be implemented includes: “a central processing unit, programmable memory, a display/input means, and means for communicating with a computer or computer network.”

As such, applicants respectfully request that this rejection be withdrawn for claims 39 and 63 and their dependents, 40, 45, 52-62, and 64-67, respectively.

35 U.S.C. § 103 Rejections

Claims 18-23, 25-27, 29-34, 39, 40, 46-50, 52-67 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, *Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures*, The Quality of Life Newsletter, January 1999-April 1999 (hereinafter “Ware”), in view of U.S. Patent No. 5,059,127 to Lewis (hereinafter “Lewis”). Claims 43, 45, and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ware in view of U.S.

Patent No. 6,067,523 to Bair (hereinafter "Bair"). Applicants respectfully traverse these rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); MPEP 2143.

Here, the Examiner has failed to establish a *prima facie* case of obviousness because the cited references fail to teach or suggest all of the limitations of the claimed invention. The pending claims all require: varying a threshold, after each question, as a function of the estimated score during the administration of the test to the patient. As explained in prior January 12, 2009 response, herein incorporated by reference in its entirety, applicants respectfully submit neither Ware, Lewis nor Bair either taken alone or in combination teaches this claim limitation of pending claims.

In fact, the Examiner has admitted that Ware does not expressly teach: varying a threshold as a function of the estimated score; and dynamically modifying the test based on an answer provided to an immediately prior question if said estimate confidence level is outside the threshold. (See 2/11/2008 Final Office Action at 3). But the Examiner then cites Fig. 3 in Ware and essentially alleges that Ware teaches these claim limitations. Applicant respectfully submits it is well settled that the Examiner cannot use hindsight reconstruction to modify the clear explicit teaching of the prior art reference to render claims unpatenable. "To imbue one of ordinary skill in the art with knowledge of the present invention, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim of the insidious effect of hindsight syndrome, wherein that which only the inventor taught is

used against the teacher.” W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983). The prior must to be judged based on a full and fair consideration of what that art teaches, not by using applicant’s invention as a blueprint for gathering various bits and modifying the pieces in an attempt to reconstruct applicant’s invention. The Examiner cannot simply change the principle of the operation of the reference or render the reference inoperable for its intended purpose to render the claims unpatentable.

Fig 3 in Ware discloses selecting most informative item to test at step 2, re-estimating health score at step 3, computing the confidence interval at step 4, and determining if stopping rules have been satisfied at step 5. If it is determined that stopping rules have not been satisfied, then it repeats steps 2-5. The pending claims require that after each question, three tasks be performed 1) re-estimate the score, 2) re-estimate the confidence interval, and 3) vary the threshold. It is clear from Fig. 3 that Ware only performs 1) and 2) after each question.

Yet in endless attempt to render the claims unpatentable, the Examiner asserts that “once the precision standard is met, the computer either begins assessing the next concept or ends the battery (considered to be form of “threshold”). (See 2/11/08 Final Office Action at 3). Even assuming *arguendo* that the Examiner’s assertion has merit, Ware clearly teaches away from the claimed invention:

“At Step 5, the computer determines whether the score has been estimated within a preset standard of precision based on CI [confidence interval]. . . . If the estimate is not precise enough the cycle is repeated. Once the precision standard is met, the computer either begins assessing the next concept or ends the battery.” (Ware at page 12, col. 1).

Whereas, the present invention requires the computer to “dynamically modify said test during the administration of said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold.” Even assuming *arguendo* that preset standard of precision is equivalent to the threshold, Ware **teaches away** from the claimed invention because Ware begins the next concept (alleged by the Examiner as being equivalent to dynamically modifying the test) once the precision standard is met.

But, in the claimed invention, the test being administered is dynamically modified when the threshold is not met. Further, contrary to the Examiner's assertion, Ware does not describe varying this "preset standard of precision" after each question, as required in pending claims. The prior must to be judged based on a full and fair consideration of what that art teaches, not by using applicant's invention as a blueprint for gathering various bits and modifying the pieces in an attempt to reconstruct applicant's invention. The Examiner cannot simply change the principle of the operation of the reference or render the reference inoperable for its intended purpose to render the claims unpatentable.

Moreover, as noted herein, Ware teaches preset standard of precision standard, which is preset, prior to the test and does not vary the preset precision standard during pendency of the test to the current test-taker based on her response. *See Ware* at 12, col 1. The Examiner's citation to Ware pg. 12, cols. 1 and 2 and emphasis that the "preset standard of precision is +/- 5.4 for the lowest scoring patients, where these patients scored near or below an established cutoff point used in screening patients . . . and the standard of precision was relaxed to +/-7.9 or less for patients at or above the 90th percentile" is equally misplaced. (emphasis added) (02/11/2008 Office Action at 3 incorporated by reference in 04/06/2009 Office Action at 4). The standard applied in the Ware evaluation was preset based on pre-screening of each patient; the threshold did not vary dynamically with the changing estimated score during the pendency of the test, as required in pending claims. It appears that the Examiner has succumbed to the lure of prohibited hindsight reconstruction to render the claims unpatentable.

Lewis also does not teach or suggest varying the threshold as a function of the estimated score during the administration of the test to the patient. Lewis actually teaches away from an *adaptive* testing method by disparaging such a method as complicated and not easily implemented. (*see e.g.*, Lewis, col. 8 ln. 61 – col. 9, ln. 13). Lewis also states that "the additional complication of an adaptive testlet selection mechanism is . . . *not particularly desirable*." (*see e.g.*, Lewis, col. 8 ln. 61 – col. 9, ln. 13). As such Lewis actually teaches away from the testing method of the claims of the present invention which require varying the threshold as a function of the estimated test score. Additionally, Lewis does not teach

dynamically modifying the test being administered if the estimated confidence level is outside the threshold. Hence, the addition of Lewis does not cure aforementioned deficiencies of Ware.

In view of the foregoing, applicants respectfully submit that the Examiner has failed to establish *prima facie* case of obviousness because the combination of Ware and Lewis does not teach all of the claim limitations and, in fact, the combination of Ware and Lewis teaches away from the claimed invention.

Furthermore, as admitted by the Examiner, the limitations recited in dependent claims 43, 45 and 51 are not taught by Ware. To cure this deficiencies, the Examiner turns to Bair. However, as with Ware and Lewis, Bair also fails to teach or suggest varying the threshold as a function of the estimated test score and dynamically modifying the test being administered if the estimated confidence level is outside the threshold. As explained in Applicants prior January 12, 2009 response, herein incorporated by reference in its entirety, Bair merely describes generating a test from a master question table and skipping certain related questions based on the answer to the first related question. See col. 11, line 45 - col. 13, line 12. Hence, the addition of Bair does not cure aforementioned deficiencies of Ware and Lewis.

In view of the foregoing, applicants respectfully submit that the Examiner has failed to establish *prima facie* case of obviousness because Ware, Lewis, and Bair independently or in combination fails teach all of the claim imitations of pending claims 18-23, 25-27, 29-34, 39, 40, 43 and 46-67, and in fact, teaches away from the claimed invention. Applicants respectfully request that the rejections be withdrawn and solicit the allowance of the pending claims.

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0624, under Order No. NY-QMET-201-US (10104949) from which the undersigned is authorized to draw.

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Respectfully submitted,

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